K070305

Section J

510k Summary

MAR 07 2007

1. Sponsor Name

RadioMed Corporation
One Industrial Way
Tyngsboro, Massachusetts 01879-1400
Telephone: (978) 649-0300 voice
(978) 649-0333 fax
Contact Individual: Gordon Roberts

2. Device Name

Proprietary Name: RadioMed™ Soft Tissue Marker
Common/Usual Name: RadioMed™ Soft Tissue Marker
Classification Name: System X-Ray, Tomography, Computed

3. Identification of Predicate or Legally Marketed Device

The predicate devices for RadioMed™ Soft Tissue Marker are:

1. Visicoil™ Marker (K031206)
2. 17, 18, 19g Needles manufactured by CP Medical (Class I – exempt)

4. Device Description

The Pre-Loaded Visicoil a sterile device, in the form of a gold coil loaded into a 17, 18 or 19g needle. The coil ranges in OD between 0.35mm and 1.2mm.

The Pre-Loaded Visicoil is packaged sterile, for single use. Sterilization is achieved by a validated EO sterilization method.

The Pre-Loaded Visicoil will be manufactured, labeled, and packaged in accordance with the current FDA QSR. To ensure compliance to specifications, upon completion of the manufacturing process the device will be inspected and tested in accordance with RadioMed standard operating procedures.

Depending on the coil size (0.35mm, 0.75mm, or 1.2mm), the Pre-Loaded Visicoil Marker will be delivered using either a 17, 18 or 19 gauge needle. The coil is supplied loaded and ready for use in the applicable needle.

5. Intended Use

The intended use and indications for use of the modified device, as described in its labeling has not changed.

The Pre-Loaded Visicoil is indicated for use to radiographically mark soft tissue for future therapeutic procedures.

6. Comparison of Technological Characteristics

The fundamental scientific technology of the modified device has not changed.

Predicate Device: Visicoil Marker

510(k) Number: K 031206

The design of the predicate Visicoil Marker is identical to the Pre-Loaded Marker. It is a gold metallic coil, ranging from one centimeter to six centimeters in length for the 0.35mm and 0.75mm versions and one centimeter to three centimeter for the 1.2mm version. Note: The 1.2mm version is nominally sized at 1.1mm and is referenced as this size on the product label.

The changes to this product include:

- Pre-Loaded in the delivery needle
- Sterilization method – Ethylene Oxide as opposed to Gamma Irradiation

7. Performance Testing

Summary of standards achieved:

FDA QSR 21 CFR Part 820 Good Manufacturing Practices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Gordon Roberts
Director, Quality Assurance and Regulatory Affairs
RadioMed Corporation
One Industrial Way
TYNGSBORO MA 01879

MAR 0 7 2007

Re: K070305
Trade/Device Name: Pre-Loaded Visicoil™ Marker
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulation Number: 21 CFR 892.1750
Regulatory Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: IYE and JAK
Dated: January 25, 2007
Received: February 5, 2007

Dear Mr. Roberts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): 070305

Device Name: Pre-Loaded VisiCoil

Indications For Use: Pre-Loaded VisiCoil is indicated for use to radiographically mark soft tissue for future therapeutic procedures.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lazzara

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070305